



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/432,503 | 11/02/1999 | THOMAS R. CECH | 15389-002611 | 1130 |

34151 7590 03/19/2004

TOWNSEND AND TOWNSEND AND CREW LLP
8TH FLOOR
TWO EMBARCADERO CENTER
SAN FRANCISCO, CA 94111

EXAMINER

RAMIREZ, DELIA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action**Application No.**

09/432,503

Applicant(s)

CECH ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 17 December 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 42,45,46,49,52-55 and 57.

Claim(s) objected to: 41 and 48.

Claim(s) rejected: 43,44,47,50,51,56 and 58-91.

Claim(s) withdrawn from consideration: _____.

8. ☒ The drawing correction filed on 3/3/2003 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

1. Claims 41-91 are pending.
2. Applicant's submission of formal drawings on 3/3/2003 is acknowledged. The drawings are approved by the Examiner.
3. It is noted that while the list of pending claims filed on 2/26/2004 refer to claims 66, 67, 70, 72-91 as previously presented, no claims 89-91 were present in the amendment filed on 4/21/2003. In addition, according to PTO records, claims 66-67, 70 and 72-88, as filed on 2/26/2004, are not the same as claims 66-67, 70 and 72-88 presented in the amendment filed on 4/21/2003.
4. The request for entering amendments to the claims filed on 2/26/2004 under 37 CFR 1.116 in reply to the Final Action Paper No. 26 mailed on 6/18/2003 is acknowledged. The proposed amendments to the claims will be entered since they are deemed sufficient to overcome the obviousness-type double patenting rejections previously applied. However, entry of these amendments is not deemed sufficient to place the application in condition for allowance for the following reasons.
5. Claims 43-44, 47, 50-51 and 56 remain rejected under 35 USC second paragraph due to the recitation of "the method of....further comprising selecting the cell from other cells because it expresses increased telomerase...". The instant claims have not been amended, therefore the rejection is maintained for the reasons of record.
6. Claims 69 and 78 remain rejected and amended claim 87 would be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, specifically since they contain new matter in the recitation of "endothelial cells" for which the Examiner has not been able to locate support. As such, the rejection is maintained for the reasons of record.
7. Claims 58-88 remain rejected and newly added claims 89-91 would be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

were deemed to contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a method of increasing the proliferation capacity of any mammalian cell *in vivo*, therefore the rejection is maintained for the reasons of record.

8. Claims 58-88 remain rejected and newly added claims 89-91 would be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the proliferative capacity of a mammalian cell in vitro by transforming said cell with a polynucleotide encoding the telomerase reverse transcriptase protein of SEQ ID NO: 2, or fragment thereof having telomerase catalytic activity when complexed with telomerase RNA, does not reasonably provide enablement for said method in vivo using any method to introduce the polynucleotide in any mammalian cell. The instant claims are drawn to a method of increasing the proliferation capacity of any mammalian cell *in vivo*, therefore the rejection is maintained for the reasons of record.

9. Claims 41, 48, 58, and 61 would be objected to due to the recitation of "polynucleotide that encodes a telomerase....protein in SEQ ID NO: 2, or fragment.." and "polynucleotide comprises the telomerase....transcriptase encoding sequence in SEQ ID NO: 1". For clarity, the claims should recite of "polynucleotide that encodes the telomerase....protein of SEQ ID NO: 2, or fragment..", "polynucleotide that encodes a telomerase....protein comprising SEQ ID NO: 2, or fragment....", or "polynucleotide comprises the telomerase....transcriptase encoding sequence of SEQ ID NO: 1".

10. Claims 41-47 and 58-60 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-8 of U.S. Patent No. 6337200. The claims as amended are now directed to a method of increasing the proliferative capacity of a mammalian cell *in vivo* and *in vitro* using a polynucleotide which encodes the telomerase reverse transcriptase of SEQ ID NO: 2 or a fragment thereof with catalytic activity when complexed with telomerase DNA. Since the method

Art Unit: 1652

of claims 7-8 of U.S. Patent No. 6337200 uses a polynucleotide which encodes a catalytic active variant of the telomerase reverse transcriptase of SEQ ID NO: 2, wherein said variant lacks at least 10 amino acids from region 192-323 or 415-450 of SEQ ID NO: 2, this rejection is hereby withdrawn.

11. Applicants submit that the vectors referred to in the claims can be used effectively for gene therapy both in vivo and in vitro. Thus, it is Applicant's contention that the claimed invention is patentable. As indicated in the interview of 3/11/2004, the claims directed to the method in vivo are not deemed adequately described and enabled in their current form. Claims which have specific limitations as to the vectors used and the target mammalian cells would require additional consideration as to whether there is a direct teaching for the use of specific vectors, such as adenovirus vectors, whether the rabbit model discussed in the Harley declaration illustrates the full scope of the claims, which vectors and target cells are enabled, as well as the cell types that can be used as targets based on the rabbit model.

12. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: 42, 45-46, 49, 52-55, 57

Claims(s) objected to: 41, 48

Claim(s) rejected: 43-44, 47, 50-51, 56, 58-91

Claim(s) withdrawn from consideration: NONE

13. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

Application/Control Number: 09/432,503

Page 5

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 17, 2004

Rebecca Long
REBECCA E. LONG
PRIMARY EXAMINER
GROUP 1600
16 00